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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K010428

1.0 **Submitter's Name and Address:**

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318
Telephone: (952)368-1323
Fax: (952)368-7610
Contact: Brent Taber

2.0 **Date Prepared:**

February 12, 2001

3.0 **Device Names:**

3.1 **Proprietary Name**

AccuTnI™ QC on the Access® Immunoassay System

3.2 **Classification Name**

Quality Control Material (assayed and unassayed) (21 CFR § 862.1660)

4.0 **Predicate Device:**

Access® AFP QC
510(k) Number: K981864

5.0 **Description:**

The Access AccuTnI QC are tri-level, ready-to-use, defined protein-based liquid controls manufactured by Beckman Coulter, Inc. Each kit contains 2 x 2.5 mL bottles for each level of control.

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6.0 Intended Use:

The Access AccuTnI QC is intended for monitoring system performance of the Access AccuTnI assay.

7.0 Comparison to Predicate(s):

The following tables show similarities and differences between the predicate identified in Section 4.0 of this summary.

SIMILARITIES to the PREDICATE

Reagent	Aspect/Characteristic	Comments
Access AccuTnI QC	Intended Use	Same as the predicate
	Value Assignment	Same method as the predicate
	Storage Temperature (Open Vial)	Same as the predicate
	Instrumentation used for Assay	Same as the predicate
	Assay Technology	Same as the predicate

DIFFERENCES from the PREDICATE

Reagent	Aspect or Characteristic	Comments
Access AccuTnI QC	Formulation	The Access AccuTnI QC is a defined protein-based product The Access AFP QC is a human serum based product
	Analytes	The Access AccuTnI QC have recombinant cardiac troponin I complex added as the analyte The Access AFP QC have human alpha-fetoprotein (AFP) added as the analyte

8.0 Summary of Performance Data:

Stability studies of the Access AccuTnI QC support the open vial stability claim of 60 days. Within-run, between-run and total imprecision of each level of the Access AccuTnI QC were less than 10%CV.

9.0 Conclusion:

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence of the Access AccuTnI QC to the Access AFP QC.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 1 3 2001

Mr. Brent Taber
Regulatory Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318-1084

Re: K010428
Trade Name: AccuTnI™ QC on the Access® Immunoassay System
Regulatory Class: I, reserved
Product Code: JJX
Dated: February 12, 2001
Received: February 13, 2001

Dear Mr. Taber:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): Not yet assigned K010428

Device Name: **AccuTnI™ QC on the Access® Immunoassay System**

Indications for Use:

The Access AccuTnI QC is intended for use in monitoring the reliability and overall performance of the Access AccuTnI assay in the clinical laboratory. The use of control materials allow the laboratorian to monitor linearity along with analytical error and imprecision.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K010428

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109) Optional Format 1-2-96